

REMARKS

In the Office Action dated December 12, 2007, Examiner Ramana withdrew rejections over references to Foley, Felt and Zhong, and she is thanked for those withdrawals. However, the current Office Action included rejections of pending claims 37-40, 42-49, 51-52, 55-62 and 64-65 as allegedly anticipated by one or both of the previously-cited Sertich reference (US 5,800,550) and a newly-cited Beyar reference (US 6,127,597). In view of the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

Claims 37, 42-47, 49, 51-52 and 55-62 Are Not Anticipated by the Sertich Reference

Examiner Ramana is thanked for withdrawing her rejection of at least claim 48 over the Sertich reference. However, the allegation in the current Office Action that claims 37, 42-47, 49, 51-52 and 55-62 are anticipated by Sertich is not borne out by the reference.

Respectfully, it is first noted that the Office Action does not include a discussion of all of the features of the rejected claims. No particular reference to any claim was given, and it appears that the language of only claim 37 was tracked. The sole allusion to the claims by number was in a list along with a statutory provision and the references. With regard to most or all of the dependent claims, no analysis at all was given in the Office Action. Respectfully, that is another reason that a proper rejection has not been made of those claims. It is "incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference." *In re Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990); 37 CFR 1.104(c)(2).

Sertich discloses an intervertebral cage or spacer that can be inserted between vertebrae, then a set of pegs is forced out of the spacer and into the adjacent vertebrae. The pegs are forced outward by turning a threaded rod so that it moves forward against their slanted surfaces. Thus,

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 7 of 16
Attr. Docket 4002-3430

rotational motion is turned into longitudinal motion by the threads on the rod, and longitudinal motion is turned into lateral motion by the slanted surfaces of the pegs.

The Office Action compared the tool 98 and its handle 100 of Sertich to the "delivery instrument" of claim 37, the threaded rod 110 to the "expandable element" of that "delivery instrument," and the pegs 70 to the recited "first portion" and "second portion" of an expandable device. The threaded rod 110 is not expanded nor is it anything that is expandable. As noted above, it merely travels within threaded bore 12 to convert rotational motion to longitudinal motion. It does not get longer, wider or otherwise bigger, but only shifts its position with respect to handle 100. In fact, no aspect of tool 98 expands or is expandable. As seen from Sertich's Figure 4, the overall length of tool 98 (from the left side of item 116 to the right side of item 118) does not change. Turning item 116 advances threaded rod 110 through handle 100, but it does not alter the size of the whole of tool 98 or any part of it.

Additionally, pegs 70 (as seen in Figure 1A) are not portions extending along an expandable device, as claim 37 recites. Rather, they extend into body 30, or essentially the opposite of along the body. They are moved outward by the longitudinal motion of the threaded rod 110 against their slanted surfaces, which outward motion is controlled by the openings 56, 60 directed into body 30. There is no expansion of any expandable element, and thus no movement of the pegs upon such expansion, as recited in claim 37.

Claim 37 also recites that expansion compresses cancellous bone in the intravertebral space. Pegs 70 are designed to penetrate into bone, not to compress it. See, e.g., column 6, lines 18-21, stating that the serrated edge shown provides less resistance to penetration. The hollow nature of the upper part of the peg is shown in Figures 1A and 1B (see also column 8, lines 15-

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 8 of 16
Atty. Docket 4002-3430

17), and Figure 1A shows only that hollow part extends out of body 30 and into bone. The Sertich device does not have structure that is expandable to compress bone.

Claims 42-47, 49, and 51-52 are all dependent from claim 37, and the Sertich reference does not anticipate them based on that dependence and/or on their own merit. For example, claim 44 recites that in the expanded configuration distal parts of the first and second portions are separated by one height, and proximal parts of those portions are separated by a height, with one of those heights being greater than the other. Viewing Figure 1A of Sertich, pegs 70 do not appear to have "distal" or "proximal" portions, unless the pegs' right-most sides (facing the numbers 56 and 84 in the drawing) could be considered "distal" since they are furthest from tool 98, and their left-most sides (facing numbers 66 and 60) could be considered "proximal." The distance between those "distal" and "proximal" portions is along the body 30, not above it, and so there is no "height" between them. Further, the distance between the first peg's "distal" and "proximal" portions is the same as that for the other peg.

Claim 45 recites that the expandable device is tapered between the two heights. No part of body 30 of Sertich is tapered in any configuration shown or suggested in the reference.

Claim 47 recites that the recited first and second portions of the expandable device have bone growth openings therethrough. The Office Action compared these portions to Sertich's pegs 70, but the pegs have no bone growth openings. The serrations in the pegs are for cutting into bone and obtaining a better grip on the bone (col. 6, ll. 18-27). The gaps are not for bone growth, but are provided so that more surface area of the peg will contact bone. There is no possibility of bone ingrowth insofar as the holes are occupied or blocked with bone tissue.

Independent claim 55 recites a delivery instrument including an expandable element. As discussed above, Sertich does not show or suggest an expandable element in its tool 98. Claim

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 9 of 16
Atty. Docket 4002-3430

55 also recites that the expandable element is expandable to move portions of an expandable device to compress bone, which has also been shown not to be found or suggested in the Sertich reference.

Claims 56-62 depend from claim 55, and are not anticipated by Sertich based on that dependence and/or on their own merit. For example, claim 56 recites that the first and second portions of the expandable device each define an outer surface with bone engagement members therealong. The only "bone engagement members" in Sertich appear to be pegs 70, but the Office Action alleged the pegs to be first and second portions of an expandable device. If the pegs are such first and second portions, then they cannot logically also be bone engagement members along their own outer surface.

Claim 57 recites that the first and second portions remain movably engaged during expansion of the expandable element. Not only is there no expandable element, the pegs 70 of Sertich operate by being pushed away from and out of contact with each other. They do not engage each other as they are being pushed.

Claims 58 and 59 recited the separate heights and taper shown to be missing from Sertich in the above discussion regarding claims 44 and 45. Claim 61 recites bone growth openings akin to those recited in claim 47, discussed above. These claims are also not anticipated by Sertich.

The above remarks are focused primarily on the view of Sertich taken in the present Office Action, and particularly to the marked-up version of Figure 1A in the Action. Previous remarks concerning the reference are not repeated for the sake of brevity, but are incorporated herein by reference insofar as they pertain to the current view of Sertich. In light of the present and prior remarks, the rejections over Sertich should be withdrawn.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 10 of 16
Atty. Docket 4002-3430

Claims 37-40, 42-49, 51-52, 55-62 and 64-65 Are Not Anticipated by the Beyar Reference

The Beyar reference discloses a toroidal vertebral disc prosthesis in the form of a balloon, as well as an expandable intramedullary treatment device. Regrettably, it was not clear as to which of those structures the Office Action relied on in its analysis, since the Office Action cited to parts of the reference concerning each device, and its text did not use any reference numerals as a guide. Applicant will endeavor to respond completely to this rejection. If Examiner Ramana feels that further issues remain after consideration of the following remarks, she is respectfully requested to provide additional information concerning her view of this reference and its relationship to the pending claims.

As noted above with respect to the Sertich reference, it is believed that the analysis with respect to Beyar does not meet the requirements of 37 CFR 1.104(c)(2). The overall length of the reference, as well as the number of devices and embodiments provided in it, make it even more important for the Examiner to particularly point out what part(s) of the reference are applicable to specific claims of this application.

The Office Action refers particularly to Figures 28-31 in Beyar. Those drawings show aspects of an inflatable intramedullary nail 310, which can be packed in a collapsed state (Fig. 29B) and inflated with high-pressure fluid to an inflated state (Fig. 29C). Figures 30A-30B show collapsed and inflated states of the same item superimposed on each other (see col. 22, ll. 14-24; col. 36, ll. 34-39). Figures 31A-31B show the item along a guide wire (col. 22, ll. 25-31).

However, the Office Action also refers to portions of the text relating to an intervertebral disc prosthesis, particularly columns 14-16 and columns 31-37. (It is assumed that the Office Action's referral to columns 21-37 is a typographical error, and column 31 was intended.) That prosthesis is a balloon only, which may have metal or other sturdy supports along with it. See,

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 11 of 16
Atty. Docket 4002-3430

e.g., col. 14, ll. 37-39 ("In the context of the present disclosure, the balloon prosthesis is referred to interchangeably either as the balloon or the prosthesis."). The balloon is rolled up longitudinally, inserted through a cannula, and then inflated with a "solidifying fluid" (see, e.g., Figures 15-16 and col. 14, ll. 43-50). The balloon is toroidal, and includes spikes for insertion into adjacent bone tissue (see Figure 14B). The balloon is not a means for expanding any other part. Rather, it is the entire prosthesis, and is the only item that is inflated.

Neither the toroidal balloon disc prosthesis nor the balloon intramedullary device has all features of independent claim 37. For example, neither structure includes both a delivery instrument with an expandable element and an expandable device removably mounted to that expandable element. The Office Action appears to suggest that a cannula or tube for inserting the balloon corresponds to the delivery instrument of the claim. It is believed that a cannula only appears in Beyar in Figures 3A-3C and 7A (item 48) and Figures 15-16 (item 160), although a type of sleeve 285 is shown in Figures 27A-27B. None of items 48, 160 or 285 have any expandable element at their respective distal portions.

With respect to the balloon intervertebral prosthesis, only the prosthesis itself is inflatable. It is inflated with a cement, polymerizing monomer, or similar fluid that solidifies within the balloon and maintains the balloon's shape and support for the vertebral motion segment. If the balloon prosthesis is considered an "expandable device," the reference shows no expandable element of a delivery instrument, as recited in claim 37. It further shows no expandable element in a cavity of the balloon prosthesis. Without an expandable element in such a cavity, there can be no movement of first and second portions of the balloon prosthesis upon expansion of an expandable element, as claim 37 also recites.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 12 of 16
Atty. Docket 4002-3430

With respect to the inflatable intramedullary nail, it is inflated by forcing saline or other fluid into it. Saline is not expandable without heat, and there is no disclosure of heating saline within the intramedullary nail. There is no expandable element that is a part of a delivery instrument related to the inflatable intramedullary nail. No expandable structure is in a cavity within the intramedullary nail. No movement of portions of the intramedullary nail occurs upon expansion of an expandable element within such a cavity.

Of course, if either the balloon prosthesis or the intramedullary nail are considered an "expandable element" on a distal portion of a delivery instrument, it is evident that no related "expandable device" as in claim 37 is shown in Beyar. The balloon prosthesis is used by itself. It is not fitted into the cavity of another expandable item, to expand it as it is inflated. Likewise, the intramedullary nail is inserted in the collapsed state into a medullary canal of a long bone, and is inflated therein to engage the bone. It does not enlarge any other device.

Claims 38-40, 42-49, and 51-52 depend from claim 37, and are not anticipated by Beyar on that basis and/or on their own merit. For example, claim 42 recites that the first and second portions define an outer surface with bone engagement members along that surface. The Office Action alleged rods on the exterior of a balloon (apparently relying on col. 34, ll. 1-6) to be such first and second portions, but that portion of the Beyar reference does not disclosed any bone engagement members on such rods. Rather, it suggests protrusions on the surface of the balloon, which is distinct from such rods (col. 34, ll. 17-18). Protrusions 153 (Figure 14B and col. 31, ll. 37-41) are for penetration into bone, and they are likewise on the surface of the balloon, not a part of any rod on the exterior of any balloon.

The height features and tapered feature of claims 44 and 45 are discussed above, and Beyar does not disclose either. The metal rods alleged to be the "first portion" and "second

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 13 of 16
Atty. Docket 4002-3430

portion” of the claim are not shown in any drawing, and their positioning on the inflation of the balloon does not appear to be discussed in the text, and so what their positioning might be is a matter of speculation. Even assuming that such metal rods might be along upper and lower surfaces of the balloon prosthesis as seen in Figure 14B of Beyar, it clear that the heights between such rods at a distal location (e.g. adjacent number 144 in Figure 14B) will be the same as a height between them at a proximal location (e.g. adjacent number 148). No stepped configuration as in claim 46 is seen in or implicit from Beyar’s disclosure as well.

Claim 47 recites bone growth openings through the first and second portions. The Office Action alleged metal rods for those first and second portions, yet there is no disclosure of any openings of any kind in such rods.

Claim 52 recites that the cavity in the expandable device opens at both distal and proximal ends of the device. As seen in Figures 14A-14B, the balloon prosthesis does not have a distal opening, and if it did, then the inflating material pumped into it via opening 148 would leak out before solidifying. Similarly, the intramedullary nail seen in Figure 29A has no proximal opening, and if it did, saline would leak out. In fact, it is likely that one could not provide sufficient saline pressure to inflate the intramedullary nail from its folded-in collapsed state if a proximal opening existed, as that pressure would go to expelling saline from the proximal opening rather than inflating the nail.

Independent claim 55, like claim 37, recites a delivery instrument that includes an expandable element, as well as an expandable device with a cavity such that the expandable element is expandable in the cavity. As explained above, if the balloon prosthesis or intramedullary nail of Beyar is an “expandable device,” there is no expandable element of a delivery instrument that is inside a cavity to expand them. Conversely, if they are considered an

"expandable element," Beyar does not disclose any other device in which they fit, and which they expand.

Claims 56-62 and 64-65 depend from claim 55, and are not anticipated by Beyar on that basis and/or on their own merit. Claim 56, like claim 42, recites bone engagement members along outer surfaces defined by the first and second portions. As discussed above, Beyar does not show or suggest such features. Claims 57, 58 and 59 include subject matter akin to the features discussed above in claims 44, 45 and 46, respectively. Claim 61 is similarly like claim 47 discussed above.

Claim 57 recites that the first and second portions remain movably engaged with each other during expansion of the expandable element. As discussed above, no expandable element as recited in claims 37 and 55 appears in Beyar. As also noted previously, there appears to be no particular discussion concerning the configuration of any rods on the exterior of the balloon prosthesis. Thus, there is no disclosure of any such rods engaging one another at all, much less remaining movably engaged when an absent expandable element is being expanded.

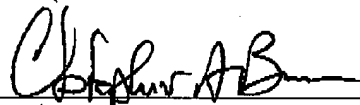
Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken by the examiner that are not specifically addressed herein. No narrowing amendments have been made, and no narrowing of the scope of the claims via the remarks above is intended or should be inferred.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 15 of 16
Atty. Docket 4002-3430

Reconsideration and passage to allowance in view of the above remarks is respectfully requested. Should it be determined that any further issues are outstanding, Examiner Ramana is encouraged to telephone the undersigned.

Respectfully submitted,



Christopher A. Brown, Reg. No. 41,642
Woodard, Emhardt, Moriarty,
McNett & Henry LLP
Chase Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137

515926

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 16 of 16
Atty. Docket 4002-3430